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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/284,297	07/05/2000	Dosuk D. Lee	04712/02000G	2121

21559 7590 08/23/2005

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EXAMINER	
LEVY, NEIL S	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/284,297	LEE ET AL.	
	Examiner	Art Unit	
	NEIL LEVY	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40,42,43,103,111- 143,145-153* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40;42;43;103,111-135,138--143,145,146,148,150-153* is/are rejected.

7)☒ Claim(s) *136,137,147 and 149* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 June 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Note is taken of claim 43 directed to a single material, rather than 1 of each of the specified categories. Also, drawings have been received.

Claims 43, 127, 128, 133, 135 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18, 21 of copending Application No. 09/993739.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the rejection of record is maintained.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple asignees. See In re Goodman, 1 1 F.3d 1 046, 29 USPQZd 201 O (Fed. Cir. 1993)', In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1 985)., In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982)., In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1 970)., and, In re Thorington, 41 8 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1 .13O(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 40, 42, 43, 11 1-1 18, 120, 127-131, 133, 134 are rejected under 35 U.S.C. 102(e) as being anticipated by Constantz, 5962028.

The rejection of record is maintained.

Constantz shows use of dry mixed & compressed components (col 5, bottom – col 6, top), then hydrated, (col 4, lines 55-57) in situ. Dry components of calcium phosphate and the instant promoter ca sources (col. 5, line 25-65) are combined (col. 5, last 2 paragraphs),Resulting in PCA. Carbonate provides increased strength (col 3, bottom) of the 1.33 Ca/P CAP(col 4, bottom). Lubricant can be added (col. 7, line 55-57), & the hardening is non-exothermic(col 7, bottom).

Neither is the claimed instant process seen as requiring successive steps, rather than combination of procedures .Examples show mixing, and milling, meeting the instant compression, since there is no claimed quantification of compression, while Constantz. (Example 2, table 3) shows compressed products. As to stoichiometry, it is less than 1.5 Ca/P (col. 4, line 61). As to supplemental materials, it can be collagen (col 6, bottom)' . Collagen is seen as meeting the requirements instantly claimed of adherence, tensile strength, and elasticity of the composite.

Claims 40, 42, 43, 1 1 1-1 14, 1 16-121, 124, 126-135, 138-140, 142, 143, 145, 146, 148, 150-153 are rejected under 35 U.S.C. 102(e) as being anticipated by Constantz et al 5782971.

See III B., Col. 8: A bioceramic of the instant claim 40 is prepared by dry mixing powders of Ca Phosphate (ACP) with promoters, Ca Carbonate, and supplemental materials, Ca phosphates then hydrated (col. 9, lines 29 -39).This can be done in situ.

Prosthetic devices and the Bioceramic, bioresorbable products are envisioned. Mixing of dry powders prior to liquid addition is disclosed as optional variation of the paste preparation (col. 5, line 1 1-28). The instant specification is no more explicit on this process as Constantz. The lubricant is water or other physiological lubricant (col. 8, line 28-31). Ca/P is as low (col. 5, lines 5-10) as .1 to 1 (less than 1.5) as instantly claimed', inclusive of amorphous Ca/ P ratios. A number of supplemental agents provide (col. 5, line 50 - line

8, col. 6) characteristics inclusive of resorption time, strength and other desirable properties and may include Ca sulfate, and phosphoric acid, thus function however they function in the instant compositions. The products are bioresorbable, biocompatible, applicable as a paste in vivo (col. 6, lines 1 1-39), to harden, or can be used as implants, or prosthetic devices (last paragraph, col. 6). Note the paste does not set up, but is injectable, at room temperature (col. 6, line 27-55) and sets at body temperature - thus, endothermîc (col. 8, lines 48-50). Active additives are at col. 6, top., Compression strength and pressure at col. 6,line 40-55. Particulate extenders are at col. 6, top - calcium sulfate', Demineralized bone is matrix Gla - protein. Claims 150, met, at col. 6 lines 47-50, and, since same components are those instantly utilized, at the same compression strength, so would the density, as of claim 151.

Claims 40, 43, 103, 111- 121,123-135, 138-143, 145,146, 148, 150-153 are rejected under 35 U.S.C. 1O3(a) as being unpatentable over Constantz-5782971 –in view of Constantz et al – 6005162.
Constantz (above) is seen as obvious, since, as indicated above, Constantz uses the instant components, mixed as powders, with lubricant fluids added to provide wet mixing, or added after mixing, followed by compression. Lyophilization is at Col. 9. However, not all supplemental components instantly claimed are discussed. These components aare optional additives used for their intended purposes to optimize the invention, & are given no patentable weight. However, 6005162 show them (col. 5, lines 43-line 67, col. 7). ACP is addressed, as the Ca/P ratio (col. 3, line 16-line 24, col. 4) , particle size, & forms of Ca-P used are within the parameters of amorphous CaP, with ratio adjustable to tailor the resorption rate.
Dry mixes are seen as storable for long periods(col. 5 line 36-43) free of liquid.
Application to sites of interest involve setting at Body temperature, in presence of physiological fluids (col 7, lines 27-38).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize an bone defect composition to prepare one of Constantz, with modification to use any of art recognized means to improve setting, healing characteristics, shown by Constantz, 6005162. Motivation to use a specific additive is shown to be a function of desired effects, & art recognized , by Constantz, 6005162 and adjuvants

and exact ratios and amounts thereof are within the purview of one in the art to attain, in order to optimize desired effects, such as control of setting, pharmacological effects,compatability, stability.

All the critical elements of the instant are disclosed. The amounts and proportions of each ingredient are result effective parameters chosen to obtain the desired effects. It would be obvious to vary the form of each ingredient to optimize the effect desired, depending upon the particular parameter of interest compatibility.

There is no non obvious and/or unexpected results obtained since the prior art is well aware of the use of ACP and the use of additives for the functionality for which they are known to be used is not a basis for patentability.

Applicant's arguments filed 6/6 /05 have been fully considered but they are not persuasive. Applicant argues in essence, all the components as now claimed are not seen in the Constantz patents. However, applicant's disclosure provides no criticality , unexpected, or unobvious results by altering the sequence of preparatory steps, to arrive at ACP compositions. In fact, Constantz does dry mix. Specific additive materials & process steps are seen as within the purview of the Artisan to achieve, are shown by Constantsz, & are not seen as a basis for patentablility. Applicant 's arguments for focus on paste & flowing by Constantz is not welll taken, since applicant's focus is the same, & only incidentally are the modes of dry preparation disclosed, to no greater degree than in the prior art.

Claims136,137,,147,149 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

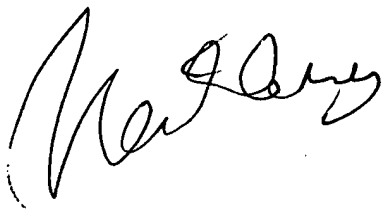
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL LEVY whose telephone number is 571-272-0619. The examiner can normally be reached on Tuesday-Friday, 7 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, THURMAN PAGE can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) (toll-free). at 866-217-9197.



NEIL S. LEVY
PRIMARY EXAMINER